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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,761	02/16/2001	Grace Yim Ngan Chan		2972

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

DATE MAILED: 02/27/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,761

Applicant(s)

CHAN ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-13 is/are allowed.
- 6) ☒ Claim(s) 1-6 and 14-20 is/are rejected.
- 7) ☒ Claim(s) 21 and 22 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claim Objections

1. Claim 8 is objected to because of the following informality: in line 4 "or" should be -- and --.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4-6, 14, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Balshüsemann (DE 4112168 A1).

Addressing Claims 1 and 14, Balshüsemann teaches an apparatus for use in gel electrophoresis, the apparatus comprising a polyacrylamide gel utilizing a buffer system comprising 0.25 M Tris titrated with HCl to pH 6.7 (col. 2, ll. 35-45). Although Balshüsemann does not state that "Tris" means Tris(hydroxymethyl)aminomethane (note an English language translation of this patent is not currently available to the examiner), as may be inferred from the product description for Trizma® hydrochloride from the *Sigma-Aldrich* catalog and from list of

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Biological Buffers from the *CRC Handbook of Chemistry and Physics*, one with ordinary skill in the art would understand "Tris" to mean Tris(hydroxymethyl)aminomethane.

Addressing Claims 4-6 and 17-19, although Balshüsemann does not mention the shelf-life of the gel, since the gel as taught by Balshüsemann has the same composition and utilizes the same buffer as claimed by Applicant it will inherently have the same properties. Furthermore, Applicant's definition of shelf-life is very broad since there is no quantifiable measure of "acceptable" and protein separations depend on several other factors than gel composition and buffer, such as the applied electrophoresis field, sample preparation, type of protein, and additional ingredients to the buffer.

Addressing Claim 20, Balshüsemann also teaches a method of performing electrophoresis using the apparatus according to claim 14. Applicant's steps of applying a sample and subjecting the gel to an electric field may be found in col. 2, ll. 17-19. electrode buffers are taught in col. 2, ll. 55-65.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2, 3, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balshüsemann (DE 4112168 A1) in view of Starzec et al. ("Several Intermediate Forms in the Processing of Rat Lutropin Subunits as shown by Sodium Dodecyl Sulphate Polyacrylamide Gel Electrophoresis," *Journal of Chromatography*, 440 (1988) 353-360), Wadström et al. ("A rapid method for separation and detection of human salivary amylase isoenzymes by isoelectric focusing in polyacrylamide gel," *Scand. J. Dent. Res.* 1976: 84: 234-239), and the CAPLUS abstract of Rosengren et al. ("A simple method of choosing optimum pH-conditions for

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electrophoresis," Electrofocusing Isotachophoresis, Proc. Int. Symp. (1977), Meeting Date 1976, 165-71. Eds. Radola et al.).

Balshüsemann teaches an apparatus for use in gel electrophoresis, the apparatus comprising a polyacrylamide gel utilizing a buffer system comprising 0.25 M Tris titrated with HCl to pH 6.7 (col. 2, ll. 35-45). Although Balshüsemann does not state that "Tris" means Tris(hydroxymethyl)aminomethane (note an English language translation of this patent is not currently available to the examiner), as may be inferred from the product description for Trizma® hydrochloride from the *Sigma-Aldrich* catalog and from list of Biological Buffers from the *CRC Handbook of Chemistry and Physics*, one with ordinary skill in the art would understand "Tris" to mean Tris(hydroxymethyl)aminomethane. Balshüsemann does not mention having Tris at 0.18 to 0.22 M and pH of 6.8 to 7.2 or Tris at 0.20 M (pH 6.7, as taught by Balshüsemann is about 7.0 as required in Claim 3). However, as shown by Balshüsemann, Starzec et al., Wadström et al., and Sims it was known at the time of the invention to provide a polyacrylamide gel utilizing Tris at a concentration and titrated with HCl to a pH either slightly below, slightly above, or overlapping applicant's claimed values. For example, as stated above, Balshüsemann teaches a polyacrylamide gel utilizing a buffer system comprising 0.25 M Tris titrated with HCl to pH 6.7 (col. 2, ll. 35-45). Starzec et al. teach a polyacrylamide gel utilizing a buffer system comprising 0.125 M Tris titrated with HCl to pH 6.8 (bottom of page 354 – top of page 355). Wadström et al. teach a polyacrylamide gel utilizing a buffer system comprising 0.4 M Tris titrated with HCl to pH 6.8 (second paragraph in the first column on page 235). Furthermore, it was known at the time of the invention to optimize the buffer properties, such as pH, as seen in Rosengren. So, barring evidence to the contrary, such as unexpected results,

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Applicant's claimed Tris concentration or concentration range and pH or pH range are within Tris and pH ranges effectively disclosed by the prior art and have been just chosen to optimize the polyacrylamide gel for its intended use.

Allowable Subject Matter

8. Claims 7-13 are allowed.

9. Claims 21 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 7: Balshüsemann does not mention how the gel was prepared so it not known if the 0.25 M Tris buffer at pH 6.7 was added to the polyacrylamide polymerization mixture (note that a full translation of Balshüsemann is not currently available to the examiner). Starzec et al. and Wadström et al. also do not mention how the gel was prepared;

b) Claims 8-13 depend directly or indirectly from allowable claim 7;

c) Claim 21: neither Balshüsemann, Starzec et al., nor Wadström et al. teach also providing TRIS and HEPES in an electrode buffer; and


d) Claim 22 depend from allowable claim 21.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Alex Noguera
February 23, 2003